Kansas Drug Utilization Review Newsletter

Health Information Designs, LLC *2nd Quarter 2018*

Welcome to the Quarterly edition of the "Kansas Drug Utilization Review Newsletter," published by Health Information Designs, LLC (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Kansas Medical Assistance Program (KMAP).

Helpful Web Sites

KMAP Web Site
https://www.kmap-state-ks.us/

KDHE-DHCF Web Site
http://www.kdheks.gov/hcf/

KanCare Web Site
http://www.kancare.ks.gov/

Fee-For-Service (FFS) Helpful Numbers

Provider Customer Service (Provider Use Only)
1-800-933-6593

Beneficiary Customer Service
1-800-766-9012

KMAP PA Help Desk
1-800-285-4978

In This Issue:

Overview of CGRP and Migraine

Overview of Migraine

Migraines are a headache disorder characterized by recurrent headaches that typically last from 2-72 hours. A migraine headache produces an intense pulsing or throbbing pain in one area of the head that can also result in nausea, vomiting, and sensitivity to light and sound. Due to the severity and duration of these symptoms, migraine headaches are often disabling. It is estimated that ~6% of men and ~18% of women experience a migraine in the United States annually. These patients commonly have recurring attacks, which are triggered by a number of different factors, including stress, hormonal changes, lighting, diet, and fatigue.

The Role of Calcitonin Gene-Related Peptide in Migraine

While the precise etiology of migraine remains unknown, it has long been recognized that occurrences of migraine headaches are accompanied by dilation of cranial blood vessels, as well as elevations of plasma levels of calcitonin gene-related peptide (CGRP). CGRP is a neuropeptide that is synthesized and released by neurons throughout the central and peripheral nervous system. Because it is a very potent microvascular vasodilator (~10 times more potent than the most potent prostaglandins) and is primarily contained in nerve fibers associated with pain processes, the primary functions of CGRP are related to pain perception and inflammatory processes around nerves. Based on the growing understanding of the role of CGRP in migraine and other research, many current hypotheses regarding migraine pathophysiology theorize a system of self-perpetuating vasodilation that is mediated in part by CGRP. In these hypotheses, the pathophysiology of a migraine is generally explained as follows:

1. Migraine triggers lead to dysfunction within the brain, causing dilation of cranial blood vessels
2. The dilated vessels activate sensory fibers of the trigeminal nerve which conveys a pain response to the brain
3. Pain responses in the brain evoke a release of CGRP and other mediators from trigeminal nerve fibers
4. CGMP & other mediators cause further vasodilation, further activating trigeminal sensory fibers, causing a repeat of the pain response cycle

Because of the growing understanding of the potential role of CGRP in migraine, drugs targeting CGRP have been in development for a number of years, the first of which was received FDA approval earlier this year.

Review of Aimovig

FDA Approval and Indication

On May 17, 2018, the FDA approved Amgen's Aimovig (erenumab-aooe) for the preventive treatment of migraine in adults. This was the first drug approved in a new class that achieves it's therapeutic effect by blocking the activity of CGRP at the receptor level.

Clinical Trial Experience

The effectiveness of Aimovig for the preventive treatment of migraine was demonstrated in three, placebo-controlled, clinical trials. All three trials evaluated the average reduction in monthly migraine days at the end of the trial, but differed in their patient population and duration.

1. The first study was 6 months in duration and included 955 participants with a history of episodic migraine. At six months, patients receiving Aimovig experienced an average reduction of 1 to 2 monthly migraine days vs. those receiving placebo.
2. The second study was 3 months in duration and included 577 patients with a history of episodic migraine. At the end of the trial, patients receiving Aimovig experienced an average reduction of 1 monthly migraine days vs. those receiving placebo.
3. The third study was 3 months in duration and included 667 patients with a history of chronic migraine. At 3 months, patients receiving Aimovig experienced an average of 2.5 fewer monthly migraine days vs. those receiving placebo.

Dosing

- 70 mg or 140 mg injected subcutaneously once monthly
- No dose adjustments provided for patients with renal or hepatic impairment

Safety Profile

- There are no contraindications to therapy listed in the manufacturer's labeling
- The only warning for in the manufacturers labeling is that packaging may contain latex
- The only listed drug known to interact with Aimovig is belimumab, as it may enhance toxic effects of belimumab
- The most noted adverse effects to therapy with Aimovig were
    - Constipation (3%)
    - Antibody development (3% to 6%)
    - Injection site reaction (5% to 6%)
    - Muscle cramps or spasms (≤2%)

References

1) Aimovig (erenumab-aooe) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2018.
2) Durham PL. Calcitonin gene-related peptide (CGRP) and migraine. Headache: The Journal of Head and Face Pain. 2006 Jun 1;46(s1)
3) Villalón CM, Olesen J. The role of CGRP in the pathophysiology of migraine and efficacy of CGRP receptor antagonists as acute antimigraine drugs. Pharmacology & therapeutics. 2009 Dec 1;124(3):309-23.
4) Russell FA, King R, Smillie SJ, Kodji X, Brain SD. Calcitonin gene-related peptide: physiology and pathophysiology. Physiological reviews. 2014 Oct;94(4):1099-142

Vaccine Awareness

August is National Immunization Awareness Month (NIAM), the purpose of which is to both celebrate vaccination benefits, as well as highlight the importance of vaccination for all people. With these goals in mind, we ask that you take the time to review the following key information laid out by the CDC regarding vaccination focusing on 4 key points:

- Vaccines protect against serious diseases
- These diseases still exist and outbreaks do occur
- Most adults have probably not received all the vaccines they need
- Vaccines are very safe

Vaccines Protect Against Serious Diseases

- Vaccines are prevent serious diseases such as influenza (flu), shingles, pneumonia, hepatitis, and whooping cough, many of which can be debilitating or even deadly.
- Some vaccines can help prevent cancer:
  - The hepatitis B vaccine can prevent liver cancer that can develop from chronic hepatitis B
  - Vaccination against HPV can prevent cervical, vaginal, vulvar and anal cancers caused by HPV infection

These diseases still exist and outbreaks do occur

- Every year, tens of thousands of adults in the U.S. needlessly suffer, are hospitalized, and even die from diseases that could be prevented by vaccines. Some examples below:
  - **Influenza**: An average of 226,000 hospitalizations and up to 49,000 deaths each year.
  - **Pneumococcal pneumonia:** ~900,000 infections, 400,000 hospitalizations, and 19,000 deaths annually
  - **Hepatitis B:** 850,000 to 2.2 million people infected
  - **HPV:** Results in ~17,000 cancers in women and ~9,000 cancers in men annually

Most Adults Have Probably Not Received All the Vaccines They Need

- According to CDC data,:
  - Only 20% of adults 19 years or older had received Tdap vaccination
  - Only 28% of adults 60 years or older had received shingles (herpes zoster) vaccination
  - Only 20% of adults 19 to 64 years at increased risk had received pneumococcal vaccination
  - Only about 44% of adults 18 years or older received a flu vaccine during the 2014-2015 flu season

Vaccines are very safe

- Vaccines are thoroughly tested before licensing and carefully monitored even after they are licensed to ensure that they are very safe.
- While some people may have allergic reactions to certain elements of some vaccines, other side effects from vaccines are typically mild and temporary

Because of the crucial role healthcare providers play in proper patient education, the CDC recommends that all healthcare providers routinely assess their patient's vaccine needs and make strong recommendations for proper vaccination. If you would like more information on the NIAM, including toolkits for communication and vaccination recommendations, please visit their site at https://www.nphic.org/niam.

References

1) Centers for Disease Control and Prevention. (2018). Recognizing National Immunization Awareness Month (NIAM). Retrieved from https://www.cdc.gov/vaccines/events/niam.html
2) Centers for Disease Control and Prevention. (2018). Vaccine Information for Adults. Retrieved from https://www.cdc.gov/vaccines/adults/index.html
3) National Public Health Information Coalition (NPHIC). (2017). NIAM Toolkit. Retrieved from https://www.nphic.org/niam

Generic Medications

Recently Approved Generic Drugs:

March 2018	April 2018	May 2018
Baclofen Injection (Gablofen) Cinacalcet (Senispar)	Miglustat (Zavesca) Ertapenem (Invanz) Clozapine ODT (Fazaclo) Everolimus (Zortress)	None

Upcoming Generic Drugs:

Generic Name	Brand Name	Anticipated Launch
Treprostinil	Remodulin	June 2018
Fentanyl sublingual tablet	Abstral	June 2018
BOP-clindamycin 2.5-1.2%	Acanya	July 2018
Dalfampridine	Ampyra	July 2018

PRST STD
U.S. Postage

Health Information Designs, LLC
391 Industry Drive
Auburn, AL 36832
www.hidesigns.com

Mailing Address Line 1
Mailing Address Line 2
Mailing Address Line 3
Mailing Address Line 4
Mailing Address Line 5